

### REMARKS

Claims 1-40 are pending in the instant application. Claims 2, 5, 6, 9-13, 15, 17-20, 22-26, 28-33, 35 and 37-40 are withdrawn from consideration pursuant to the Restriction Requirement made in the Office Action mailed 27 August 2003. At the outset, Applicant gratefully acknowledges the indication of allowable subject matter in claims 4 and 34. However, the Examiner's position on claim 14 is inconsistent with the indication of allowability of claim 34. Applicant presumes the Examiner intended to indicate claim 24 to be allowable, which is commensurate in scope with claim 4.

In the Office Action, claims 1, 3, 7, 8 and 16 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Pat. No. 6,478,804 to Vargas, et al. (hereinafter, "Vargas"). Claims 21, 27, and 36 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,893,369 to LeMole (hereinafter, "LeMole"). Claims 1 and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,972,024 to Northrup, III, et al. (hereinafter, "Northrup III"). Claim 1 (and its dependents) are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement of the terms "means [for] implementing an anastomosis" and "means for causing said wire". Claim 34 is rejected under 35 U.S.C. § 112, second paragraph for indefiniteness, specifically lack of antecedent basis for the term "said suture wire". Claim 21 is objected to for a minor informality relating to the phrase "for causing said wire".

**Formal Matters**

With respect to the objection of claim 21, by the above amendment this claim is amended to read "~~for~~causing said wire". This amendment is to correct a minor editorial oversight only, and does not affect the scope of the claim. The claim now properly characterizes the recited method step. Applicant respectfully submits that the objection has been obviated and kindly requests favorable reconsideration and withdrawal.

**The Claims Are Definite and Fully Enabled**

With respect to the rejection of claim 34 under 35 U.S.C. § 112, second paragraph, for indefiniteness, by the above amendment, claim 34 has been amended to read "end of said ~~suture~~-wire". The term "wire" finds proper antecedent basis in claim 21. It is noted that this a broadening amendment with respect to claim 34 as originally filed. However, no new matter has been added. Applicant respectfully submits that the rejection has been obviated and kindly requests favorable reconsideration and withdrawal.

With respect to the rejection of claim 1 (and its dependents) under 35 U.S.C. § 112, first paragraph, for lack of enablement, Applicant respectfully traverses the rejection. Regarding the phrase (as amended) "means for implementing an anastomosis", the specification at page 1, line 22 states "the attachment or anastomosis of the vessels..." Therefore, throughout the specification, each means for attaching vessels shall be read as a means for implementing an anastomosis. These means are detailed throughout the specification. However, for the convenience of the Examiner these are recited at least in part here, and include but are not limited to, sutures (p. 16, lines 16-22),

bio-adhesive, staples or other specialized fasteners (p. 14, lines 7-10), some combination of two or more of these (p. 17, line 12 – p. 18, line 21), or any equivalent of the foregoing under 35 U.S.C. § 112, para. 6.

Turning to the phrase “means for causing said wire to cut through the adjoining walls”, this is similarly described in detail in the specification. However, for the convenience of the Examiner these are recited at least in part here, and include but are not limited to, moving back and forth of the wire (p. 15, lines 1-4), equipping the wire with an abrasive coating (p. 15, lines 4-6), application of RF energy (p. 15, lines 6-10), upward force on the wire positioned within the vessel (p. 17, lines 1-10), some combination of two or more of these, or any equivalent of the above under 35 U.S.C. § 112, para. 6.

Therefore, Applicant respectfully submits that the claims are fully enabled by the specification. Favorable reconsideration and withdrawal of the rejection is kindly requested.

**The Claims Are Patentably Distinguished Over The Prior Art**

On the merits of the claims, Applicant respectfully traverses all rejections for at least the reasons set forth below.

With respect to Vargas, Applicant respectfully submits that the disclosure cited in the Office Action does not teach the asserted elements. Claim 1 recites, *inter alia*, a wire having one end inserted into said target vessel by puncturing the wall of said vessel and exiting said vessel by puncturing the wall at a spaced location. The Office Action avers that this feature is taught in Fig. 20, element 116.

Vargas shows at Fig. 20 a staple 114 having a staple end 116, and anvil 104 having bending arms 108 to secure a graft vessel to a target vessel at the anastomosis site. According to Vargas, the opening in the target vessel has already been formed, incision 118. Therefore, the staple 114 does not puncture the wall of the target vessel at two spaced locations (see Fig. 22). Therefore, claim 1 is distinguished over Vargas.

Further, claim 1 recites means for causing said wire to cut through the adjoining walls of said vessels. By contrast, Vargas recites no means for causing the wire to cut through the adjoining walls of the vessels within the region of contact. Therefore, Claim 1 will be seen as clearly distinguished over Vargas.

Claims 3, 7, and 8 each depend, either directly or indirectly, from claim 1. They are offered as patentable for at least the same reasons as independent claim 1. However, they are also separately patentable. For example, claim 3 recites the wire being longitudinally reciprocated so as to cut through the vessel walls. In contrast, there is no teaching or suggestion that the staple in Vargas is reciprocated. Rather, it is merely inserted in one direction only. Claim 9 recites the wire being manipulatable so as to align and contact said vessels with each other. In contrast, there is no teaching or suggestion that the staples of Vargas are capable of being manipulated to align and contact the vessels with one another. Claim 16 recites the anastomosis comprising stitching sutures about the joining sides of said vessels to abut the graft vessel to the target vessel. The Office Action offers Fig. 33 as teaching this feature. However, Fig. 33 of Vargas is a different method, and uses the sutures in place of the staples, not in addition to them.

Therefore, Applicant respectfully submits that the rejection over Vargas has been obviated, and kindly requests favorable reconsideration and withdrawal.

Turning to LeMole, the reference teaches a procedure for forming an anastomosis where the graft vessel is flared at its distal end, and sutured to the wall of the target vessel. Subsequently, a device positioned within the graft vessel forms the opening between the graft and target vessels. The Office Action reads the suture (24) on the claimed wire. However, claim 21, as amended above, recites "implementing an anastomosis between said vessels ~~in adjacent~~ said region of contact between said vessels..." As defined by the claim, the method of the present invention defines a region of contact as the area of the vessel along the wire between the two spaced locations. The region of contact is to become the opening for fluid communication between the target vessel and the graft vessel. The anastomosis, or attachment of the vessels, is formed adjacent that region of contact.

In contrast to the claim, LeMole lacks any teaching or suggestion that suture 24 defines the region of contact where the opening between the graft vessel and the target vessel. Moreover, the rejection is inconsistent with itself. According to the Office Action, with respect to claim 36, the suture 24 is read on two distinct elements of the claim, creating the fluid flow passageway and suturing about the joining sides of the vessels. However, the suture cannot read on two elements, both the wire of claim 21 and the sutures of dependent claim 37. *See, Lantech, Inc. v. Keip Machine Co.*, 32 F.3d 542, 31 USPQ2d 1666 (Fed. Cir. 1994).

Therefore, Applicant respectfully submits that the rejection over LeMole has been obviated, and kindly requests favorable reconsideration and withdrawal.

Turning to Northrup, III, the reference teaches forming an anastomosis by using a suture (20) connecting a leading needle (40) and a trailing clip (60). The needle and

suture guide the clip into position, which closes to secure the anastomosis. However, in contrast to claim 1, the opening in the target vessel has already been formed before the introduction of the suture (see, e.g., Figs. 7-9, Col. 5, lines 24-32). Therefore, there is no teaching of a wire doing so as recited in the claim.

Further, with respect to claim 14, the needle (40) does not define the distance between the two spaced locations as asserted. It can clearly be seen in Figs. 2-6 and 7-9 that the spaced locations are drawn together by the suture and clip following the puncture. Further, the spaced locations are not on the same vessel, as recited in the claims. Therefore, claim 14 will be seen as further distinguished over Northrup, III.

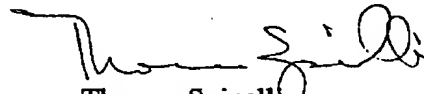
Therefore, Applicant respectfully submits that the rejection over Northrup, III, has been obviated, and kindly requests favorable reconsideration and withdrawal.

#### Conclusion

In light of the foregoing, Applicant respectfully submits that all claims recite patentable subject matter, and kindly solicits an early indication of allowability. In accordance with the Restriction Requirement, Applicant kindly request rejoinder of all species claims, as generic claims 1 and 21 are shown as allowable, *supra*. However, Applicant further submits that claim 24 reads on the elected species (Species 1B, longitudinal reciprocations) and that claim 24 is generic.

If the Examiner has any reservations in allowing the claims, and believes that a telephone interview would advance prosecution, he is kindly requested to telephone the undersigned at his earliest convenience.

Respectfully Submitted,



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